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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/746,746	12/22/2000	Stephen D. Ainsworth	ACS 54804 (23571)	6882

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EXAMINER

BAXTER, JESSICA R

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 12/22/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/746,746

Applicant(s)

AINSWORTH ET AL.

Examiner

Jessica R Baxter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,8-29 and 31-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,8-29 and 31-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 2, 11 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,652,573 to von Oepen in view of U.S. Patent No. 6,033,433 to Ehr et al.

Von Oepen discloses the claimed invention except for the bounded aperture disposed in the link. The bulged sections in the linked portions can be pulled from one another to create a larger opening in the wall of the stent (FIG. 1 and Column 1 lines 46-53). Ehr teaches an alternate embodiment to the bulged sections of von Oepen. The spiral like structures (FIG. 25) of Ehr allow the stent to expand when the structures straighten out. It would have been obvious to one having ordinary skill in the art to replace the bulged sections of von Oepen with the spiral construction of Ehr as an alternate embodiment to allow the stent to expand.

3. Claims 3, 4, 5, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over to von Oepen '573 in view of Ehr et al '433.

Von Oepen, as modified, discloses the invention as claimed except for the shape of the bounded aperture. It would have been an obvious matter of design choice to change the shape of the bounded aperture of von Oepen, since it has been held to be within the general

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skill of a worker in the art to select a known shape on the basis of its suitability for the intended use as a matter of obvious design choice.

4. Claims 12, 13, 17, 18, 24, 25, 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over von Oepen '573 in view of Ehr et al. '433 as applied to claims 1, 2, 8, 10, 11 and 36 above, and further in view of U.S. Patent No. 5,843,175 to Frantzen.

Von Oepen, as modified, discloses the claimed invention except for the tapered and radiused link portion. Frantzen teaches providing tapered and radiused portions to increase the flexibility of the stent in the tapered and radiused portions (Column 13 line 61-Column 14 line 55). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of von Oepen, as modified, with the tapered and radiused portions in order to increase the overall flexibility of the stent.

5. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over von Oepen '573 in view of Ehr et al. '433, and further in view of U.S. Patent No. 5,843,175 to Frantzen.

Von Oepen, as modified, discloses the invention as claimed except for the shape of the bounded aperture. It would have been an obvious matter of design choice to change the shape of the bounded aperture of von Oepen, since it has been held to be within the general skill of a worker in the art to select a known shape on the basis of its suitability for the intended use as a matter of obvious design choice.

6. Claims 8, 9, 10, 14, 20, 22 and 23 rejected under 35 U.S.C. 103(a) as being unpatentable over von Oepen '573 in view of Ehr et al. '433 as applied to claims 1, 2, 8, 10, 11 and 36 above, and further in view of U.S. Patent No. 6,190,403 to Fischell et al.

Von Oepen, as modified, discloses the claimed invention except for the undulating link. Fischell teaches that an undulating link is provided in order to allow the stent to be

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compressed to a smaller diameter without having portions of the stent overlap and increases the stent's flexibility (Column 4 lines 47-61). It would have been obvious to one having ordinary skill in the art to modify the device of von Oepen, as modified, to include undulating links to increase the flexibility of the stent and to permit the stent to be crimped to a smaller diameter without having sections of the stent overlap.

7. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over von Oepen '573 in view of Ehr et al. '433 as applied to claims 1, 2, 8, 10, 11 and 36 above, and further in view of U.S. Patent No. 5,925,061 to Ogi et al.

Von Oepen, as modified, discloses the claimed invention except for the stent being made out of a shape memory alloy or a pseudo-elastic metal alloy. Ogi teaches that a variety of materials may be used to make a stent (Column 6 lines 14-32). It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the device of von Oepen, as modified, out of a shape memory or pseudo-elastic metal alloy since these are well known materials in the art.

8. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over von Oepen '573 in view of Ehr et al. '433, further in view of Frantzen '175 as applied to claims 12, 13, 17, 18, 24, 25, 37 and 38 above, and further in view of Fischell et al. '403.

Von Oepen, as modified, discloses the claimed invention except for the undulating link. Fischell teaches that an undulating link is provided in order to allow the stent to be compressed to a smaller diameter without having portions of the stent overlap and increases the stent's flexibility (Column 4 lines 47-61). It would have been obvious to one having ordinary skill in the art to modify the device of von Oepen, as modified, to include

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undulating links to increase the flexibility of the stent and to permit the stent to be crimped to a smaller diameter without having sections of the stent overlap.

9. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over von Oepen '573 in view of Ehr et al. '433, further in view of Frantzen '175 as applied to claims 12, 13, 17, 18, 24, 25, 37 and 38 above, and further in view of EP 0 806 190 to Rolando et al.

Von Oepen, as modified, discloses the claimed invention except for the varying cross sections of the plurality of struts that form the cylindrical rings. Rolando discloses varying the cross sections in order to achieve optimal characteristics of plastic deformability and resistance to stress, which may close the stent (see Column 11 line 31- Column 12 line 20). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the cross sections of the plurality of struts of the modified invention of von Oepen in order to optimize the characteristics of plastic deformability and resistance to stress.

10. Claims 27, 28, 31, 34, 35 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/32543 to Penn et al. in view of Ogi et al. '061, and further in view of Frantzen '175.

Penn discloses a stent comprising a plurality of cylindrical rings (see FIG. 1) interconnected to form a stent, at least one flexible link (see FIG. 8 sidewalls 734 and 740) attaching each cylindrical ring to an adjacent cylindrical ring, and an undulating link (see FIG. 8 strut 770) within the wall of the ring (see Page 15 line 29- Page 16 line 7). Penn, as modified, discloses a stent comprising a plurality of cylindrical rings having a plurality of U-shaped portions (see FIG. 9 wall 860), Y-shaped portions and (see FIG. 9 wall 860 and portion 836) W-shaped portions (see FIG. 9 wall 850). Penn does not disclose a bounded aperture disposed in the link between the cylindrical rings. Ogi teaches that an aperture

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provides more compressibility in the direction aligned with the longitudinal axis of the stent and increases the bendability in radial directions (see Column 7 lines 52-67). Frantzen teaches providing tapered and radiused portions to increase the flexibility of the stent in the tapered and radiused portions (Column 13 line 61-Column 14 line 55). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the stent of Penn with the aperture of Ogi in order to provide more compressibility in the direction aligned with the stent and to provide the stent of Penn with the radiused and tapered portions of Frantzen with the tapered and radiused portions in order to increase the overall flexibility of the stent.

11. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/32543 to Penn et al. in view of Ogi et al. '061, and further in view of Frantzen '175, further in view of Fischell et al. '403.

Penn, as modified, discloses the claimed invention except for the undulating links with a plurality of bends. Fischell teaches that an undulating link is provided in order to allow the stent to be compressed to a smaller diameter without having portions of the stent overlap and increases the stent's flexibility (Column 4 lines 47-61). It would have been obvious to one having ordinary skill in the art to modify the device of Penn, as modified, to include undulating links to increase the flexibility of the stent and to permit the stent to be crimped to a smaller diameter without having sections of the stent overlap.

12. Claims 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/32543 to Penn et al. in view of Ogi et al. '061, and further in view of Frantzen '175, further in view of EP 0 806 190 to Rolando et al.

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Penn, as modified, discloses the claimed invention except for the varying cross sections of the plurality of struts that form the cylindrical rings. Rolando discloses varying the cross sections in order to achieve optimal characteristics of plastic deformability and resistance to stress, which may close the stent (see Column 11 line 31- Column 12 line 20). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the cross sections of the plurality of struts of the modified invention of Penn in order to optimize the characteristics of plastic deformability and resistance to stress

Response to Arguments

13. Applicant's arguments with respect to claims 1-6, 8-29 and 31-35 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Jessica R Baxter
Examiner
Art Unit 3731


jrb


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